REMARKS

It is noted that the Examiner has denied Applicant's claim of priority under 35 U.S.C. §120 for co-pending patent application Serial No. 09/064,000 as allegedly not providing an enabling disclosure for methods of treating arthritis or avascular necrosis and accords an effective filing date of June 5, 2002 for the instant application. Favorable reconsideration is requested in view of the following remarks.

Regarding Applicant's claim of priority for parent application Serial No. 09/064,000, the Examiner stated the following at pages 2 and 3 of the outstanding Office Action:

> Based upon information given by applicant and an inspection of the applications, the examiner has concluded that the disclosure of the prior-filed application, Application No. 09/064,000, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

The above-mentioned "information given by applicant" is not identified by the Examiner; however, Applicant believes that such information consists of three applications and their relationship thereof. Applicant continues to rely upon such information to perfect its claim of priority in the instant application. The Examiner did not identify what applications were "inspected" to determine denial of the priority claim. Applicant has reviewed the two parent applications underlying the priority claim and is at a loss to understand how the Examiner failed to identify relevant information in such parent applications pertaining to the claimed invention.

Rather than identify any specific claims that were not enabled by the parent applications, the Examiner stated at page 3 of the outstanding Office Action that:

> ..it is incumbent upon the applicant to provide the serial number and specific page number(s) of any patent application filed prior to 06/05/2002 which specifically supports the

> particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 06/05/2002.

Assuming that the Examiner was referring to the claims under examination rather than all pending claims, Applicant directs the Examiner's attention to the following disclosure in parent application Serial No. 09/064,000: Page 20, line 10 to page 21, line 15; page 37, line 19 to page 38, line 2; page 40 lines 27 and 28; page 42, line 28 to page 43, line 3; page 47, line 22 to page 48, line 15; page 49, lines 18-28; and page 50, lines 7-12. Such disclosure directs and enables a person skilled in the medical art how to make and use the claimed invention, i.e., how to treat arthritis with a cellular growth factor to reduce inflammation and how to correct avascular necrosis by using a cellular growth factor to grow a blood vessel. Applicant considers that all limitations of claims 159, 161-167, 188-190, and 193-199 are supported and enabled by the above-cited disclosure.

Applicant finds it difficult to understand how the above disclosure could have been overlooked during the Examiner's inspection of the applications. It would appear that the Examiner has neglected to read pertinent disclosure specifically pertaining to arthritis and avascular necrosis, as well as disclosure pertaining to the use of growth factors, such as cells, to grow blood vessels. Perhaps the Examiner did not appreciate that Applicant disclosed cells as comprising a growth factor species within the bounds of the disclosed invention and thus did not read the entire application with the understanding of one skilled in the medical art. Without such appreciation, the Examiner's reading becomes selective and ignores relevant information regarding the genus growth factor and other disclosed growth factor species enumerated. Once the Examiner reads the disclosure as a whole, as mandated by current case law, there should be no further question regarding priority. See In re Anderson, 471 F.2d 1237, 176 USPQ 331, (CCPA 1973); In re Johnson and Farnham, 555 F.2d

1008, 194 USPQ 187, 195 (CCPA 1977); and In re Fuetterer, 319 F.2d 259, 265, 138 USPQ 217, 223 CCPA 1963).

In view of the above remarks, Applicant believes that the claim of priority is appropriate and confirmation thereof is respectfully requested.

Claims 164 and 196 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner took issue with the meaning of the term "blood stem cell" by stating that, "...such term is not precisely defined either in the art or in the instant specification."

The Examiner is once again referred to page 40, lines 27 and 28 of the parent application Serial No. 09/064,000 and to page 17, lines 9 and 10 of the instant application, where it is stated that:

> Living stem cells are harvested from the bone marrow, the blood of the patient, or from cell culture techniques.

The above statement provides context for the term "blood stem cell" and is self-explanatory to those skilled in the medical art because stem cells are disclosed to be useful in the practice of the disclosed invention. In any event, Applicant conducted a brief internet search for the phrase "list stem cells harvested from blood" using the Google search engine. About 378,000 results were obtained. A copy of page one of the above-mentioned search is attached hereto as Exhibit A. Applicant considers that the search results constitute compelling, probative evidence that the disputed term is well known in the medical art and is not indefinite. Accordingly, Applicant requests reconsideration of this rejection.

Claims 159-167 and 188-199 were rejected under 35 U.S.C. §112 first paragraph, for lack of enablement. Favorable reconsideration of the rejection is requested in view of the following remarks.

At the outset, it is noted that the Examiner, at page 4 of the outstanding Office Action, acknowledges that treating avascular necrosis by administration of bone marrow stem cells is enabling. Hence, it appears that claim 195 should not have been included in the above rejection.

When evaluating enablement, Applicant believes that the following general principles are applicable and should be considered by the Examiner.

First, there is no requirement that an applicant's claims set forth the practical limits of operation for the invention. One must look to the specification, not the claims, in determining compliance with the first paragraph of the statute. It is clear that the Examiner, in determining compliance with the enablement requirement of the statute, has ignored the scope of enablement provided by the specification as a whole. The Examiner's limited evaluation of Applicant's specification constitutes error. See In re Anderson, supra; In re Johnson and Farnham, supra; and In re Fuetterer, supra.

It is evident that the Examiner has failed to consider the disclosure provided by Applicant's specification as a whole. The appropriate factual determination is whether the instant specification conveys to one skilled in the art that Applicant invented the claimed subject matter. The Examiner erroneously restricted such factual determination to only the claimed species of growth factor. Such determination ignores those portions of the specification describing a broader generic invention and the use of other growth factor species, such as genes/nucleic acids; the treatment of other organs; and specific artery growth sites. Applicant is entitled to have the entire disclosure considered in determining compliance with 35 U.S.C. §112, first paragraph. As demonstrated below, the selective, limited evaluation performed by the Examiner is clearly erroneous and fails to comport with current law.

Second, the first paragraph of the statue requires nothing more than objective enablement, and it is of no importance whether such teaching is set forth by use of illustrative examples or by broad terminology. As a general matter, an application's disclosure, which contains a teaching of how to make and use the invention in terms which correspond in scope to those used in describing the invention sought to be patented, is considered to be in compliance with the enabling requirement of the statue. In re Marzocchi, 439 F.2d 220, 169 USPQ 367, 369-370 (CCPA, 1971). Further, "Section 112 does not require that a specification convince persons skilled in the art that the assertions therein are correct." [Emphasis added]. In re Robins, 429 F.2d 452, 166 USPQ 552 (CCPA, 1970).

With the above-mentioned legal principles in mind, Applicant submits that there are three fundamental factors to consider when determining whether the instant specification contains disclosure that enables a skilled person in the medical art to make and use the claimed invention. When these factors are reasonably considered and evaluated through the eyes of a skilled medical person, Applicant believes that there can be no doubt that the instant specification contains an enabling disclosure. The three fundamental factors are discussed below.

First, there is a considerable body of disclosure provided by the subject application relating to Applicant's generic invention of treating arthritis and avascular necrosis with a growth factor, including growing a blood vessel. Also included in the disclosure are growth factor species, such as stem cells and other disclosed growth factor species, suitable for practicing the claimed processes. In addition, administration techniques are disclosed for administering such growth factors and species to achieve the results of the invention.

The Examiner's attention is directed to Applicant's specification at page 4, lines 1-5; at page 4, line 8 to page 5, line 20; to page 9, lines 20-22; to page 13, lines 6-13; to page 17, line 2 to page

20, line 8; to page 21, lines 23-24; to page 22, line 5 to page 24, line 15; to page 26, line 3 to page 27, line 3; to page 28, lines 12-22; to page 29, lines 8-14; to page 32, line 20 to page 37, line 21; and to page 44, lines 7-17, where a substantial body of disclosure is provided to persons skilled in the medical art regarding using a growth factor to for grow soft tissue, such as a blood vessel, in a human body and to the treatment of arthritis and the avascular necrosis form of arthritis. The specification describes a class of growth factors that may be used to treat arthritis and avascular necrosis. Such growth factors broadly and specifically includes genes, nucleic acids, a patient's own cells (autologous cells), or universal cells, e.g., stem cells (mononuclear bone marrow cells), etc., all of which are described to promote tissue growth, including blood vessels, through differentiation and morphogenesis.

Particular attention is directed to the following portions of the specification identified in the preceding paragraph, which confirm that cells are used as a growth factor to grow a blood vessel, such as an artery.

- Page 4, lines 9-11: The term "growth factor" is defined as encompassing "compositions and living organisms which promote the growth of hard --- or soft tissue in the body of a patient." Moreover, the unchallenged fact that cells promote the growth of soft tissue independently establishes that a cell is a growth factor specie.
- Page 4, lines 13-14: One skilled in the art would recognize that the specie "living organisms" includes cells.
- Page 26, line 3 to Page 27, line 3: Organs and/or tissues can be formed using the patient's own cells. A cell nutrient culture may or may not be utilized depending on the desired functional outcome (i.e., growth of an artery...). It is clear that when a

> cell nutrient culture is used the growth factor for growing an artery must be a cell. Organs and/or tissues can be formed without the patients' own cells if universal donor cells, such as germinal cells, are utilized. During reimplantation, one of the patient's own cells is returned to the patient. During implantation, a cell not originally obtained from the patient is inserted on or in the patient. In the example above, if germinal cells (and in some cases, stem cells) are utilized, a direct differentiation and morphogenesis into an organ can occur *in vivo, ex vivo,* or *in vitro.*

In summary, Applicant believes that a reasonable reading of the above passages leads to the inevitable conclusion that the specification discloses the use of a cellular growth factor (cells) to treat arthritis and avascular necrosis.

The Examiner erroneously considered only the disclosure regarding enablement as it specifically relates to the elected growth factor species, cells. The Examiner's improper selective reading, which ignores Applicant's broad and specific disclosure, i.e., pertaining to the genus growth factor and to other disclosed, but non-elected, growth factor species, is clearly erroneous under current law. See In re Anderson, supra; In re Johnson and Farnham, supra; and In re Fuetterer, supra. The Examiner is not permitted to wear blinders and focus solely upon a single elected species and ignore the scope of enablement provided by the specification as a whole, which includes the genus and other disclosed non-elected species. Otherwise, following a restriction requirement, the Examiner's enablement evaluation of the disclosure becomes erroneously and narrowly focused upon the elected species; thereby causing enablement issues to be treated formalistically rather than substantively. Enablement issues require a reasoned evaluation of the entire disclosure in the eyes of a person skilled in the art aware of the state of the art at the time the application was filed. There should be no doubt that the instant specification, taken as a whole and properly read and understood

by one skilled in the art, meets the statutory requirement for enablement under current law.

Second, the Examiner has not taken issue, nor can issue be taken, with the fact that the administration techniques and administered growth factors disclosed by Applicant were individually old and well known as of the filing date of the instant patent application. The growth factors and administration techniques disclosed by Applicant were routinely employed in the medical art, but not in the claimed combination, at the time the instant application was filed. Hence, given that the administration techniques and growth factors were known at the time the application was filed, little if any, detailed description of these techniques and growth factors is required to provide enabling disclosure to a skilled medical person.

Third, while the Examiner has neglected to identify the level of skill in the art in connection with the factors enumerated in In re Wands, 858 F2d. 731, 737; 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988), Applicant points out that the skill level is very high when it is considered that many years of education, training, and experience are required in the medical field to attain such a very high skill level. The instant specification is addressed to and is understood by highly skilled and trained persons in the medical art.

Once the above-identified relevant growth factors set forth in the subject specification are properly considered in their entirety, Applicant believes that there should be no question that one skilled in the medical art is enabled to make and use the claimed invention. This conclusion is reinforced, as noted above, by the fact that the growth factors and administration techniques, but not the inventive results, were well known when the instant application was filed. MPEP Section 2164 states that the purpose of the enablement requirement is to describe the claimed invention in such terms to permit one skilled in the art to make and use the invention. Such Section cautions that detailed procedures for making and using the invention may not be necessary if the description of the

invention itself is sufficient to permit those skilled in the art to make and use the invention. MPEP Section 2164.01 states that:

> A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F2d. 660, 661, 18 USPQ 2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F2d. 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986) cert denied, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F2d. 1452, 1463, 221 USPQ 481, 489, (Fed. Cir. 1984).

Applicant believes that the above caution is especially relevant to the instant factual situation where there was a very high level of skill in the art at the time the instant application was filed and that all the growth factors, methods, and apparatus needed to practice the invention were well known at the time of the invention. Thus, Applicant submits that the instant disclosure clearly enables one skilled in the medical arts to make and/or use the full scope of the claimed invention without undue experimentation because a reasonable consideration of the three above-delineated factors and the interaction thereof leads to the inevitable conclusion that the disclosure is enabling.

The Examiner has the burden to establish and support by convincing objective evidence a *prima facie* case of lack of enablement. Applicant, for reasons set forth below, submits that the Examiner has not met such burden.

To meet such burden, it is incumbent upon the Examiner to determine what subject matter each claim recites, i.e., the scope of protection sought for each claim. The scope of dependent claims are properly determined with respect to 35 U.S.C. §112, fourth paragraph. See MPEP Section 2164.08. Applicant points out that it is plainly evident the Examiner failed to consider the disclosure provided by the subject specification as a whole in determining compliance with the enablement requirement of the statute. The appropriate factual determination is whether the instant specification reasonably directs one skilled in the art how to make and use the claimed subject matter. The

Examiner erroneously restricted the factual determination underlying the enablement issue to the elected cell species of growth factor and, thusly, ignored those portions of the specification describing a broader generic invention and that related to other disclosed species. For example, the Examiner committed clear error in omitting disclosure relating to the genus "growth factor" and the disclosed species "gene." A proper consideration of such terms clearly supports enablement. Applicant is legally entitled to have the entire disclosure considered in determining compliance with 35 U.S.C. §112, first paragraph. See In re Anderson, supra; In re Johnson and Farnham, supra; and In re Fuetterer, supra. Further, it is well settled that the test for enablement must take into consideration that which is known in the prior art – that a patent should preferably omit that which is well known/understood in the particular art to which the claims are directed. See MPEP Section 2164.01 and the authorities cited therein.

Applicant notes that on pages 5-8 of the outstanding Office Action that the Examiner has categorized a number of factors allegedly supporting a finding of lack of enablement. Such factors are remarkably similar to those contained in MPEP Section 2164.01(a). However, the Examiner omits the factor relating to the skill level in the art. Such omission is clear error because assessment of the skill level is a paramount factor in any competent evaluation of enablement and its impact must necessarily be considered in a meaningful evaluation of the other factors.. It is apparent that a skilled person requires less direction/guidance, less or no working examples, etc. than a person having a lower skill level. In the instant situation, there can be no doubt that the skill level is very high because many years of education, training, and experience are required to practice in the medical field.

Throughout the enablement rejection, including the analysis presented under In re Wands, the Examiner repetitively referred to the many types of arthritis to be treated and to the state of the

development of cellular therapies for arthritis. Such comments appear to unduly complicate the issue of enablement because the scope of the claimed subject matter was not properly evaluated and thus apparently not understood by the Examiner. Claims 159-167 are directed to treating a symptom or sign of arthritis, i.e., inflammation. It is commonplace to use drug therapy as a first line treatment in reducing the inflammation resulting from arthritis. Treatment of a symptom or sign, as opposed to curing the underlying cause or causes of a disease, is believed to be comparatively routine for a skilled medical person; and thus markedly less experimentation and complexity is involved in developing and practicing such symptomatic treatment. Causes of arthritis are well known and have been characterized for many years. For example, broken bones, infection, autoimmune disease, as well as general wear and tear on the body, are known causes. Obviously, many of such causes are not readily curable. However, treatment of the symptom(s) or sign(s) of arthritis, such as inflammation, is of great assistance to the patient. The Examiner is urged to properly consider the scope of these claims in making an evaluation of enablement.

The Examiner, at page 5 of the outstanding Office Action, purports to follow the case law summarized in In re Wands, supra. In a similar fashion to the omission mentioned in the preceding paragraph, the Examiner has failed to list and evaluate all of the Wands factors. Noteworthy in this regard is the omission of the skill in the art. As mentioned in MPEP Section 2164.01(a), all evidence related to the Wands factors must be weighed by the Examiner (emphasis added). Obviously, the Examiner has failed to comport with the direction contained in such section of the MPEP. Thus, the Examiner's selective discussion of only some of the Wands factors is fatally flawed and cannot be probative of the issue of enablement. The Examiner is reminded that the decision in In re Wands led to the grant of a patent, as the Court found that the PTO's determination of unpredictability was not supported by the evidence in the record. In reversing the PTO, the court specifically noted that the

evidence in the record supported a finding of predictability. The Court further noted that the skill level in the art was high and that known materials were utilized in the practice of the invention in weighing the evidence. The instant fact situation is similar to that of In re Wands because the skill level is also high and known administration techniques and known materials are also utilized in the practice of the invention. Accordingly, the Examiner must also consider and give weight to such factors in the instant case.

Regarding the factors considered in the Examiner's partial evaluation, speculation and generalized statements have been set forth, rather than objective evidence in support of the conclusion that the disclosure does not enable one skilled in the art to make and use the invention. Evidence, rather than the Examiner's speculation, is required to establish a *prima facie* case of lack of enablement. In this regard, the sole evidence relied upon by the Examiner is the following quotation attributed to Joel Boyd, M.D. in 2006:

> The ability to give patients a simple injection into the knee that could restore the meniscus and prevent the inevitable progression to osteoarthritis *would be* a significant advancement in the treatment of knee pain (emphasis added).

The Examiner considered that the quotation implied that there was considerable uncertainty remaining in the field of cellular therapy for osteoarthritis. It is noted that Dr. Boyd's quotation relates to restoring the meniscus, while claims 159-167 are directed to using cells to reduce inflammation in arthritis patients and claims 188-199 are directed to using cells for growing blood vessels to treat avascular necrosis. Hence, the quotation lacks a nexus with the claimed invention. Dr. Boyd's statement is not probative of enablement and can be accorded no weight as objective evidence regarding the claimed invention.

In the discussion of the Wands factor regarding the amount of direction or guidance present, the Examiner, at page 7 of the outstanding Office Action, appears to have erroneously required that working examples be provided by stating that, "Furthermore, even these teachings are general and prophetic—no working examples are provided." As set forth in an earlier portion of the instant Amendment, the first paragraph of the statue requires nothing more than objective enablement; and it is of no importance whether such teaching is set forth by use of illustrative examples or by broad terminology. As a general matter, an application's disclosure, which contains a teaching of how to make and use the invention in terms which correspond in scope to those used in describing the invention sought to be patented, is considered to be in compliance with the enabling requirement of the statue. In re Marzocchi, supra. Further, "Section 112 does not require that a specification convince persons skilled in the art that the assertions therein are correct." [Emphasis added]. In re Robins, supra.

Applicant believes that the Examiner's discussion on pages 7-8 of the outstanding Office Action regarding the alleged quantity of experimentation is inapt because such discussion is not germane to the quantity of experimentation that would be required to make and use the invention described by Dr. Elia. Instead, the Examiner has speculated upon an unknown amount of experimentation that could be involved as the art evolves. Once this issue is brought into proper focus, it is readily apparent that one skilled in the medical art would require little, if any, experimentation to make and use Dr. Elia's disclosed invention because the administration techniques and materials were individually well known in the art and the skill level is very high. Consequently, a skilled person would find ample guidance and direction in the portions of the instant specification identified at an earlier portion of this Amendment.

In summary, Applicant believes that the Examiner's conclusion regarding a lack of enablement, which is based upon a flawed analysis resulting from an erroneous and incomplete reading of Applicant's disclosure, a flawed and incomplete analysis of the Wands factors, and a lack of sound, objective evidence, when considered *vis-à-vis* the evidence of enablement provided by Applicant's specification, fails to establish a *prima facie* case of lack of enablement under current law. Rather, the conclusion is speculative and thereby amounts to no more than the Examiner's opinion. Thus, this rejection should be withdrawn.

Claims 159, 160 and 188-192 were rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,827,289 (hereinafter "the '289 patent"). This rejection, as indicated by the Examiner, could be overcome by amending the claims to recite that the growth factor is a cell. Applicant submits that the instant amendment to independent claims 159 and 188 responds to the Examiner's indication, and the rejection of claims 159, 160, and 188-192 in view of the '289 patent should be withdrawn.

Claims 159-164, 167, 188-196, and 199 were rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,300,127 (hereinafter "the '127 patent"). For the record, Applicant notes that the '127 patent is not identified on Notice of References Cited, Form PTO-892. The Examiner is respectfully requested to so identify the '127 patent to make the record complete.

As a preliminary point, it is noted that the '127 patent has a filing date of July 29, 1998 and claims the benefit of two (2) provisional patent applications. Applicant believes that the instant application is entitled to a filing date of April 21, 1998 for reasons set forth in an earlier portion of the instant Amendment regarding the priority claim. Hence, the '127 patent, having a later U.S. filing date than the instant application, has not been established as a competent reference by the Examiner. If the Examiner believes that subject matter relevant to the claims is disclosed in either or

both of the provisional applications and has been carried forward into the application underlying the '127 patent, it is incumbent upon the Examiner to identify and explain the relevance of such subject matter.

In any event, Applicant believes that the claimed subject matter is novel over the '127 patent for the following reasons. The '127 patent specifically teaches reimplanting cells transfected with nucleic acid that encodes LMP or HLMP for inducing new bone in treating avascular necrosis in the hip or knee. The '127 patent does not teach implanting non-transfected cells for any therapeutic purpose, much less, to treat arthritis by reducing inflammation (claim 159) or to grow blood vessels (claim 188). Moreover, claim 159 calls for inserting cells, such as mononuclear bone marrow cells, which are described in the specification to control cell migration and thus prevent inflammatory cells from migrating into the arthritis afflicted areas. Accordingly, the '127 patent clearly does not respond to the subject matter of claim 159. Further, it is clear that the '127 patent discloses using cells that only promote bone growth in treating avascular necrosis and does not disclose Applicant's claimed therapeutic method of using cells that promote blood vessel growth in treating avascular necrosis as called for in claim 188. Perforce, the '127 patent cannot reasonably be said to respond to the subject matter of claims 159-164, 167, 188-196 and 199 within the purview of §102 of the statute.

Claims 159-163 and 167 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,835,377 (hereinafter "the '377 patent").

Applicant believes that the claimed subject matter is novel over the '377 patent for the following reasons. The '377 patent is limited to isolating and subsequent implanting the mesenchymal stem cell fraction derived from human bone marrow for cartilage formation, not a reduction of inflammation, as called for by claim 159. Further, it is clear that the '377 patent does

not teach the concept of using whole bone marrow stem cells for any therapeutic purpose, much less Applicant's method of reducing inflammation caused by arthritis. Moreover, as specifically pointed out earlier, the subject matter of claim 159 is fully supported (§112, first paragraph) in parent application Serial No. 09/064,000, which bears a filling date of April 21, 1998. Accordingly, Applicant submits that the '377 patent is not a competent prior art reference and, perforce, the §102 rejection based on this reference should be withdrawn.

From the foregoing remarks, Applicant submits that the instant application is in condition for allowance, and a Notice to such effect is respectfully requested. Should the Examiner have any questions or require additional information or discussion to place the application in condition for allowance, a phone call to the undersigned attorney would be appreciated.

Respectfully submitted,

Dated: 05/31/07

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EXHIBIT A

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Either way, though, it's unlikely that menstrual-**blood stem cells** will turn ... the point that "**Stem cells harvested** from young women's menstrual **blood** have ...
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